UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LABORATORIOS LIOMONT, S.A. DE C.V.,

Plaintiff,

v.

OUTLOOK THERAPEUTICS, INC., f/k/a ONCOBIOLOGICS, INC.,

Defendant.

COMPLAINT AND JURY DEMAND OF LABORATORIOS LIOMONT, S.A. DE C.V

Civil Action No. ( )

Plaintiff LABORATORIOS LIOMONT, S.A. DE C.V., by way of this Complaint, states as follows:

NATURE OF THE COMPLAINT

1. This is primarily a breach of contract suit involving a certain Strategic Co-Development, License and Supply Agreement dated as of June 25, 2014, as amended (the "Strategic Agreement") between LABORATORIOS LIOMONT, S.A. DE C.V. ("Liomont"), and OUTLOOK THERAPEUTICS, f/k/a ONCOBIOLOGICS, INC. ("OTI") in which Liomont claims due $3,000,000 it paid for no result. The Strategic Agreement provided that OTI would develop two separate biosimilar products, take them through Phase III clinical trials and obtain licensure from the FDA or EMA[1], and Liomont would manufacture and market those products in Mexico. Because OTI abandoned its efforts to develop the two products, in favor of devoting its time, money and resources to develop a third and separate product at the apparent direction of its principal investor GMS Tenshi Holdings Pte. Limited, now known as BioLexis Pte. Limited,

[1] FDA is the Food and Drug Administration in the United States and EMA is the European Medicines Agency of the European Union.

("BioLexis"), Liomont did not receive the two products in accordance with the Strategic Agreement, nor the return of its $3,000,000, constituting material breach of the Strategic Agreement.

PARTIES

2. Plaintiff Liomont is a company organized under the laws of the United Mexican States and has its principal place of business at Edificio Espacio Santa Fe, Carretera México-Toluca 5420, Piso 12, Col. El Yaqui, Delegación Cuajimalpa, 05320 Ciudad de México, Mexico.

3. Defendant OTI is a corporation organized under the laws of the State of New Jersey, U.S. and has its principal place of business at 4260 U.S. Route 1, Monmouth Junction, New Jersey 08852.

4. Collectively, Liomont and OTI are defined as the "Parties."

JURISDICTION AND VENUE

5. This Court has original subject matter jurisdiction pursuant to 28 U.S.C. § 1332 based on diversity of citizenship between citizens of different states and countries, and because the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

6. This Court has supplemental subject matter jurisdiction over Liomont's state law claims because those claims are so integrally related to Liomont's claims over which this Court has original jurisdiction, inasmuch the federal and state claims arise from a common nucleus of operative facts, and would ordinarily be expected to be tried in one judicial proceeding. Accordingly, resolution of all claims in this Court furthers judicial economy pursuant to 28 U.S.C. § 1367.

7. This Court has personal jurisdiction over OTI pursuant to Article 13.8 of the Strategic Agreement, in which the parties agreed to this venue, which New York law recognizes as an enforceable choice of forum clause pursuant to Gen. Oblig. Law §5-1402, in that there is more than $1,000,000 involved and the non-resident parties have agreed to submit to jurisdiction.

8. Venue for this action properly lies within this Judicial District pursuant to 28 U.S.C. § 1391 because the Parties agreed to exclusive jurisdiction in the United States District Court for the Southern District of New York and have waived objections to the venue or forum.

ALLEGATIONS COMMON TO ALL COUNTS

9. Biosimilar products as defined in the Strategic Agreement are products containing or comprised of certain identified biologic compounds for which an abbreviated filing could be used to obtain regulatory approval in the relevant country or legal jurisdiction, as applicable (to the extent such an abbreviated filing pathway is available in such country or jurisdiction), and regulatory approval pursuant to such abbreviated filing would be granted based on a claim of statistical equivalence or non-inferiority, or any other standard upon which the applicable Regulatory Authority will review such abbreviated filings, with respect to the biosimilar reference product, regardless of the filing pathway actually used or planned to be used.

10. On or about June 25, 2014, OTI and Liomont entered into the Strategic Agreement referenced in Paragraph 1, for the development and manufacture of two biosimilar products, namely, ONS-3010 (a biosimilar of Humira®) (“ONS-3010”) and ONS-1045 (a biosimilar of Avastin®) (“ONS-1045”) and the pharmaceutical products related thereto (collectively, the “Licensed Products”).

11. Because OTI had expertise in the development and manufacture of biosimilar products for distribution and licensing; and Liomont had expertise in the sale and distribution of pharmaceutical drugs in Mexico, this provided the rationale for the Parties entering into this Strategic Agreement for the purpose of codeveloping and commercializing these biosimilar products.

12. Under the terms of the Strategic Agreement, OTI granted to Liomont certain royalty-bearing rights and licenses for the research, development, manufacture and use in Mexico of a biosimilar version of any pharmaceutical product, in any dosage form, formulation, presentation or package configuration that is commercialized or undergoing research or pre-clinical or clinical development that contains or comprises, in part or in whole, a certain monoclonal antibody based on or derived from OTI cell lines for the Licensed Products. In addition, OTI granted the right for Liomont exclusively to conduct marketing and commercialization activities for the Licensed Products in Mexico.

13. In addition, OTI granted to Liomont within Mexico a non-sublicensable license of all of its rights and licenses under certain defined in-licensed technology, and all intellectual property rights related thereto, to the extent required to enable Liomont to (a) establish a manufacturing production process for the Licensed Products in Mexico, and (b) distribute, market and commercialize the Licensed Products in Mexico. OTI remained solely responsible for all financial obligations to third parties under the Strategic Agreement. During the term of the Strategic Agreement, OTI was precluded from granting any other license of the in-licensed technology or any intellectual property rights related thereto to any third party within Mexico.

14. The Strategic Agreement also provided for manufacturing technology transfers from OTI to Liomont within thirty (30) calendar days of notification by Liomont to OTI of the request. However, without the completion of the development and manufacture of the Licensed Products, such transfers would be meaningless and without value.

15. The Strategic Agreement defined "Commercially Reasonable Efforts" in Section 1.1.16 to mean:

> with respect to either Party, the application by such Party, consistent with the exercise of its prudent scientific and business judgment, of diligent efforts and resources to fulfill the obligation in issue with respect to any Licensed Product, consistent with the level of efforts such Party would devote to a product at a similar stage in its product life as such Licensed Product and having profit potential and strategic value comparable to that of such product, taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, past performance, the regulatory environment and competitive market conditions in the therapeutic area, safety and efficacy of such Licensed Product, the strength of its proprietary position and such other factors as such Party may reasonably consider, all based on conditions then prevailing. Commercially Reasonable Efforts of any Party shall not mean that such Party guarantees that it will actually accomplish the applicable objective.

16. The Strategic Agreement further provided, in Section 4.1, for development programs, such that "promptly following the Effective Date [June 25, 2014], by using Commercially Reasonable Efforts," the Parties were to "commence or continue a program of non-clinical (if applicable) and clinical development of" each of the Licensed Products , for use in each of their respective fields within Mexico, and to develop and commercialize the Licensed Products through Phase III Clinical Trials and Regulatory Approval in each relevant legal jurisdiction.

17. More specifically, OTI was obligated to use Commercially Reasonable Efforts to meet certain specified milestones regarding the Licensed Products pursuant to Section 4.6.2 of the Strategic Agreement:

> Oncobiologics shall use Commercially Reasonable Efforts to achieve all of the clinical, scientific and manufacturing development milestones for the Biosimilar products containing or comprising the Biologic Compounds listed in Schedule 1.1.5, including but not limited to quarterly technical updates, manufacturing cost updates and Regulatory Authority submissions and approvals, in accordance with the target completion dates set forth in the applicable Development Plan developed by the Alliance Managers, and pursuant to Section 4.4.

18. Key to this obligation was OTI's responsibilities under such development program (as defined in the Strategic Agreement) to conduct successfully Phase I and Phase III clinical trials as defined in the Strategic Agreement.

19. Although Liomont paid for the "End of Phase I" milestone for the ONS-3010 biosimilar, the Phase I results for such biosimilar were incorrect. Shortly after Liomont paid for achievement of the milestone, Liomont discovered and reported to OTI that there were serious problems in the results concerning the ONS-3010 biosimilar, namely, that the value of one of the critical quality attributes did not meet the required specifications. OTI acknowledged the problem and told Liomont it would need to engage in an alternate process [clarify what means close or above] ("Process B") to comply with the requirements to initiate a Phase III study since its first process (so-called "Process A") produced an antibody with the above-mentioned quality concern. However, OTI never finalized the development of this process nor the complete characterization of the resulting antibody. Liomont offered to perform the characterization itself but OTI refused. Even if OTI had provided the ONS 3010 producing cells to Liomont as they were, those cells could not be used unless Process B were revisited and the characterizations completed. In order to continue, Liomont would have had to invest yet another estimated $250,000 to $300,000 just to determine if the product resulting from Process B even had the possibility of becoming a biosimilar.

20. OTI's unilateral suspension of its development of these two Licensed Products constituted a failure by OTI to exercise Commercially Reasonable Efforts as defined and required under the Strategic Agreement, to fulfill its obligations regarding the Licensed Products. As set forth below, OTI decided to suspend such development because it elected to change its development strategy without notice to, and consent of, Liomont.

21. In reliance on the contractual obligations of OTI, Liomont fulfilled its own obligations to make payments to OTI, and made all of its payments due predicated on the development of the Licensed Products, which payments total $3,000,000 USD in accordance with the terms of the Strategic Agreement for all of OTI's obligations under the Strategic Agreement, including the purposes of (i) participating in the development by OTI of the Licensed Products at its New Jersey facility and (ii) obtaining rights as exclusive licensee in Mexico of OTI's technology to market, distribute and eventually manufacture the Licensed Products in Mexico.

22. Under the itemization of the payments, pursuant to Article 7 of the Strategic Agreement, Liomont was required to pay an upfront license fee of $750,000 for each of the Licensed Products, totaling $1,500,000. Those payments were made.

23. In addition, as further consideration, Liomont was obligated to make "development milestone" payments of $250,000 per each of the Licensed Products for Labscale Analytical Comparability, and another set of payments of $500,000 per each of the Licensed Products for End of Phase I. These totaled $1,500,000 payments and were made. Combined with the initial combined licensing fee down payment of $1,500,000, Liomont paid $3,000,000 USD.

24. Separate and apart from the failure of OTI to deliver acceptable and competent results for Phase 1, it also unilaterally decided to "back burner" the development of the Licensed Products for which Liomont had paid. The first confirmation that Liomont had that OTI was interrupting all work for the Licensed Products (ONS-3010 and ONS-1045) was verbal communication from OTI's president, Larry Kenyon, in December 2018.

25. Furthermore, Liomont learned that OTI had changed its strategy for product development, and that the reason that the Licensed Products were never completed was because OTI ceased to work on development of the Licensed Products to have them meet contractual requirements, due to OTI's unilateral shift of focus, resources, time, money and attention to the development of another biosimilar product, known as ONS-5010 (the "New Product"), for the sole benefit of BioLexis, its investor, and promoted by BioLexis, which had begun investing in OTI in 2017, rather than the Licensed Products. The New Product is an ophthalmic formulation of bevacizumab to treat certain retinal diseases; bevacizumab is also the main ingredient of ONS-1045, one of the Licensed Products in which Liomont had invested half of the fees it paid to OTI. Consequently, it was not only OTI's failure to correctly complete Phase I for ONS-3010, but also OTI's suspension of development activity on both of the Licensed Products in favor of the New Product, that demonstrated it was not exercising Commercially Reasonable Efforts to develop the Licensed Products as required under the Strategic Agreement.

26. Despite OTI's failure to satisfy the milestones for the Licensed Products, for which it had nonetheless been paid, or to make further efforts to develop the Licensed Products, on or about November 6, 2018, it announced publicly that it had "advanced three product candidates into clinical development." This included the New Product, which was not

one of the two Licensed Products. This was acknowledged in OTI's own press releases and filings with the Securities and Exchange Commission and information publicly disclosed to OTI's investors.

27. In addition to its failure to utilize Commercially Reasonable Efforts to develop the Licensed Products, OTI also breached the Strategic Agreement by causing a "material adverse event." A "Material Adverse Event" is defined in Section 1.1.41 of the Strategic Agreement to mean, in relevant part, "any fact, circumstance, condition or information, including without limitation any notice or other communication from the FDA or the EMA, other than as has been heretofore disclosed to LIOMONT, which would or might materially affect (a) the value to Oncobiologics or LIOMONT of the Biologic Compounds or the related Licensed Products, Intellectual Property Rights, Oncobiologics Inventions or Oncobiologics Technology."

28. The acts and omissions of OTI (e.g., unilateral interruption of work, lack of due diligence and attention, and cessation of further work regarding Licensed Products) halted the development and manufacture of the Licensed Products, and OTI focused instead its time, money and resources to the development of the New Product for its own benefit and that of BioLexis, thereby constituting a Material Adverse Event under the Strategic Agreement.

29. Liomont notified OTI of its obligations to exercise Commercially Reasonable Efforts, but OTI failed to change its conduct. Accordingly, on April 23, 2019 Liomont gave notice to OTI declaring material breach of the Strategic Agreement and also the occurrence of a Material Adverse Event thereunder.

30. In a subsequent series of communications between the parties, OTI admitted its breach of the Strategic Agreement to Liomont by stating that "the next milestone of clinical trials [of the Licensed Products] was not achievable." OTI then purported to cancel

development of the Licensed Products and otherwise repudiate the Strategic Agreement, constituting material breach and entitling Liomont to its remedies.

31. The OTI prioritization of the New Product at the expense of and prejudice to Liomont, accompanied by the failure and refusal by OTI to perform any of its contractual obligations for further development of the Licensed Products in accordance with the provisions of the Agreement, effectively made Liomont's expectations under the Strategic Agreement worthless and deprived Liomont of the benefit of its bargain. OTI has retained the money paid to it for services and products it did not deliver.

FIRST COUNT: BREACH OF CONTRACT

32. Liomont repeats each of the allegations set forth in Paragraphs 1-31 as though realleged herein in their entirety.

33. The Strategic Agreement constituted a binding agreement between the parties, which OTI breached, damaging Liomont.

34. Pursuant to Section 12.8.1, in the event of a breach by OTI, OTI is obligated to promptly return to Liomont all data and materials in its possession containing or comprising any confidential information of Liomont relating to the Licensed Products, promptly deliver to Liomont all data and materials in its possession containing or comprising any information relating to the Licensed Products, and repay to Liomont the full amount of the fees paid by it to OTI under Sections 7.1 and 7.2.

35. Liomont has been damaged in the amount of the $3,000,000 USD (three million United States dollars) it has paid to OTI and is entitled to its return based on the breach by OTI as outlined above, as well as the identified data and materials.

SECOND COUNT: BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

36. Liomont repeats each of the allegations set forth in Paragraphs 1-35 as though realleged herein in their entirety.

37. OTI owed Liomont a duty to act in good faith and conduct fair dealing, and it breached that duty, which breach of duty proximately cause Liomont's damages.

38. OTI created a duty to Liomont by taking its money and continuing to retain money that was expressly for the development and manufacture of a marketable product, and continuing to retain that money while ostensibly committing to develop both Licensed Products, including but not limited to alternative and correct testing to improve the production process for ONS-3010, and otherwise be able to comply with all of the quality requirements that were needed for Phase III completion for both Licensed Products. Furthermore, OTI represented to Liomont that OTI would seek approval from the FDA for such changes in order not to repeat a Phase I process with ONS-3010. This never happened. OTI continued to represent to Liomont that it was addressing the issue, and despite communications to seek resolution, OTI to this date still has not finished the development of the Licensed Products, has not returned the monies paid it, and essentially repudiated its agreement.

39. By unilaterally determining to give priority to the New Product and ceasing or suspending further development of the Licensed Products, OTI deprived Liomont of the benefit of its bargain and otherwise prevented performance and breached its duty to Liomont.

40. As a result, Liomont has been damaged in the amount of the $3,000,000 USD (three million United States dollars) it has paid to OTI and is entitled to its return.

THIRD COUNT: UNJUST ENRICHMENT

41. Liomont repeats each of the allegations set forth in Paragraphs 1-40 as though realleged herein in their entirety.

42. By virtue of the above-pleaded facts, (1) OTI was enriched, (2) at Liomont's expense and (3) it is against equity and good conscience to permit OTI to retain what is sought to be recovered.

PRAYER FOR RELIEF

WHEREFORE, Liomont requests this Court enter judgment on all counts as follows:

1. In the amount of $3,000,000 USD for the full amount of the fees paid by Liomont to OTI, plus interest, costs of suit, as well as consequential, incidental and special damages and attorneys' fees to the extent allowed by law;
2. Ordering OTI to return to Liomont all data and materials in its possession containing or comprising any and all confidential information as defined in the Strategic Agreement of Liomont relating to the Licensed Products;
3. Ordering OTI to deliver to Liomont all data and materials in its possession containing or comprising any information relating to the Licensed Products; and
4. For such other relief as the Court deems proper and appropriate.

JURY DEMAND

Pursuant to Fed. Rule Civ. Proc. 38, Plaintiff LABORATORIOS LIOMONT, S.A. DE C.V. demands a trial by jury as to all issues so triable.

Dated: July 20, 2020

Respectfully submitted,

CLARK HILL PLC

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